TENNESSEE CONTROLLED SUBSTANCE DATABASE

DATA REPORTING MANUAL
Effective December 2006

Optimum Technology, Inc. Contact Information
866-683-9771
tnrxreport@otech.com

TENNESSEE CONTROLLED SUBSTANCE DATABASE

In accordance with Tennessee Annotated Code §53-10-304 the Tennessee Department of Commerce and Insurance has established a program to monitor the prescribing and dispensing of Schedule II, III, IV & V controlled substances. The program will begin for all dispensers on December 1, 2006. The program requires dispensers who are licensed by the State of Tennessee, who dispense controlled substances in schedule II, III, IV and V within or from outside of the State of Tennessee and who are treating patients in the State of Tennessee to submit the required information. The program covers the entire state and requires all dispensers to report at least twice a month. Both resident and non-resident pharmacies are required to report.

REPORTING THE DATA

Dispensers will report the required dispensing information to Optimum Technology, Inc. (Optimum), a private contractor that will collect all data and manage the technical aspects of the program. Optimum will forward verified data to the Tennessee Board of Pharmacy.

Toll-free number for Optimum: 866-683-9771
Email for technical assistance: tnrxreport@otech.com

The data reporting website will be available on December 1, 2006.

Such reporting without individual authorization by the patient is allowed under HIPAA, 45CFR § 164.512, paragraphs (a) and (d). The Tennessee Board of Pharmacy is a health oversight agency and Optimum will be acting as an agent of the Tennessee Board of Pharmacy in the collection of this information.

IMPLEMENTATION SCHEDULE AND REPORTING TIMELINES

For all dispensers:
Initial reporting period—December 1, 2006
Initial Reporting Deadline— December 25, 2006

Subsequent reporting:
All transactions must be submitted at least twice monthly. The deadline for reporting dispensing between the 1st and 15th of each month is the 25th of that month. The deadline for reporting dispensing between the 16th and the last day of the month is the 10th of the next month. Dispensers are encouraged to report prior to the deadline in order to have time to correct any rejected submissions. Dispensers who so choose may report more frequently than twice a month, for example, weekly or daily.

REPORTING PROCEDURES

Only Schedule II-V prescription dispensing information is to be reported. All dispensers who are licensed by the State of Tennessee and who dispense Schedule II-V controlled substances are required to submit the information by one of the five (5) following data submission options.

1. Prescription Upload

www.tnrxreport.com is the secure website address for uploading data to Optimum which utilizes 128-bit encryption. Dispensers must be able to access the secure website via an internet connection either in the pharmacy, or at the location that is responsible for transmitting data, e.g. a main office or corporate office of the pharmacy. Internet Explorer v6.0 should be used to access the Data Collection Portal.

The submitted file must be in ASAP r.5/95 format (as shown on pages 8-9). The file name should be your username (for pharmacies and dispensers, your DEA number), followed by the date of submission and followed by .DAT. Therefore, if your DEA number is *AB01123456* and you are submitting on December 1, 2006, the file would look like this: AB*01123456120106.dat*.

Please inform your software vendor that you will need to be able to upload your data in the ASAP r.5/95 format as a .DAT file.

Your username and temporary password access is provided in the cover letter for this manual.

2. CD-Rom, CD-R, CD-RW, DVD or 3 1/2" Diskette (Please be sure to include a completed transmittal form with the CD or diskette.)

Submit information in the American Society of Automation in Pharmacy rev. 5/95 (ASAP r.5/95) format. A line feed and carriage return is required at the end of each record.

The file name should be your DEA number followed by .DAT (example: AB*01123456.dat*)

The external media label must contain: Pharmacy/Submitter Name, DEA number, and the number of prescriptions

A Program Transmittal Form (Attachment 1) should accompany external media submissions. The dispenser should make copies of the enclosed, blank Program Transmittal Form for future use. The dispenser may also wish to keep a copy of the completed form for its records.

These media forms must be mailed to:
Optimum Technology, Inc.
Attn: Data Collection
100 E Campus View Blvd
Suite 380
Columbus, OH 43235

3. Universal Claim Form

A dispenser, who does not have an automated record keeping system capable of producing an electronic report in a format described above, may submit prescription information on the industry standard Universal Claim form via a link on the prescription upload website: www.tnrxreport.com

A sample of the information required to fill out this form is attached (Attachment 2).

To Access the UCF Manual Entry screen in the data collection portal:

1. Login to www.tnrxreport.com with your username and password.
2. Single click left mouse button on Upload Center.
3. Single click left mouse button on Manual Entry
4. As explained in the 'WHAT DATA IS MANDATORY, WHAT IS OPTIONAL**?'** section, the dispenser must have at least mandatory data available to enter manual prescriptions.

4. Secure FTP

Chain Pharmacies and Community Pharmacies with multiple facilities may submit one data transmission on behalf of all of their facilities. In fact, the program prefers that chain pharmacies and community pharmacies with multiple facilities submit one transmission with the data for all of their facilities. They may do so utilizing the secure FTP procedure. If they wish to do so, they must appoint one point of contact for all of their data submissions. **Chain pharmacies should seek direction from their corporate offices concerning how their data will be reported.** Corporate offices and their software vendors should contact Optimum at: **tnrxreport@otech.com** or by calling 866-683-9771 for the user name and password. The URL is ftps.tnrxreport.com

5. Zero Reports

If a dispenser dispenses no prescriptions in Schedules II, III, IV or V during a reporting period, a "zero" report must be submitted. This must be done via a link on the prescription upload website: www.tnrxreport.com

To Access the Zero Reporting screen in the data collection portal:

1. Login to www.tnrxreport.com with your username and password.
2. Single click left mouse button on Upload Center.
3. Single click left mouse button on Submit Zero Report.
4. Select the Zero reporting period from the 'Date From' dropdown.
5. Single click left mouse button on Submit button.

Alternative Reporting Methods

The Controlled Substance Database Advisory Committee has approved an alternate form of reporting controlled substance data. This alternative reporting will utilize the Universal Claim Form which will then be mailed to Optimum Technology. The Director of the Tennessee Board of Pharmacy may administratively approve the use of the Universal Claims Form, but regulations require extraordinary circumstances in order to receive approval. The dispenser should submit a "Request a Waiver for Electronic Reporting Form" (Attachment 3) by providing a detailed explanation of the extraordinary circumstances that necessitate the accommodation of this circumstance.

Rejections

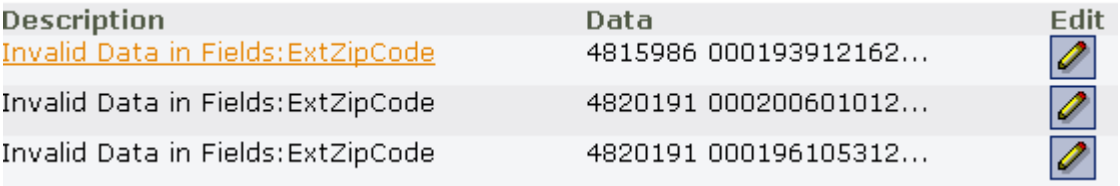
The Data Collection Portal will validate record by record. If the total rejected records exceed the threshold determined by the state, the entire file will be rejected. If the threshold is not exceeded, those records which do not meet the validation requirements will be rejected. The records which do meet the validation requirements will be accepted. The submitter will be notified, via email or by fax of the reason for rejection. Optimum is not authorized to modify any data; therefore, the dispenser will be required to correct and resubmit the rejected records or the entire file if necessary. Please read the following section on how to view and make corrections to the rejected prescriptions through the Data Collection Portal.

Correcting File Upload Errors:

The Data Collection Portal will validate record by record and reject only those records which do not meet the validation requirements. The dispenser can view the reason for rejection for each prescription record and can make correction to the rejected prescriptions through the data collection portal.

View File Upload Errors:

1. Login to www.tnrxreport.com with your username and password.
2. Single click left mouse button on Upload Center.
3. Single click left mouse button on File Upload.
4. Single click left mouse button on the appropriate file name listed under Uploaded Files.
5. Error messages are listed under the Description column.
6. Single click left mouse button on the error message.
7. Example:



Prescription Corrections:

There are two options to correct the data as detailed below.

1. Correct the data in your prescription software and then regenerate and upload the data.
    a. Please note this process may result in duplicate records because a portion of the records originally submitted were accepted. The duplicate records occurring as a result of duplicate file uploads require no action on the part of the pharmacy or dispenser.

2. Correct the data online via the Data Collection Portal. This type of correction is manually performed and is useful when there are minimal errors.
    a. To correct the errors using File Upload Errors, do the following:
        i. Follow the steps described in the '**View File Upload Errors'** section.
        ii. Single click left mouse button on Edit icon  located on the right.
        iii. Make the appropriate corrections to the prescription.
        iv. Single click left mouse on the Submit button.
        v. If additional errors exist, single click left mouse on the Back to Exceptions button.
        vi. Repeat the process for each error received.
    b. Confirm all errors are corrected, do the following:
        i. Single click left mouse button on File Upload.
        ii. The Errors column should now be zero. If not take appropriate actions.
        iii. Verify this by accessing the File Upload Errors screen and verify the records processed field.

ASSISTANCE AND SUPPORT

Optimum is available to provide assistance and information to individual pharmacies, chain pharmacies, software vendors, and other entities required to submit data. Technical support is available to meet the program requirements. Questions concerning interpretation of technical and compliance matters may be referred to Optimum. Dispensers are advised to first contact their software vendor to obtain modifications and instructions on compliance and participation. Software vendors may also contact Optimum directly for assistance.

The Controlled Substance Advisory Committee will act as the final interpreter of regulations. Unresolved disagreements between a dispenser and the vendor will be resolved by the Controlled Substance Database Advisory Committee.

Controlled Substance Database Contact Information:
For questions: call the Tennessee Board of Pharmacy (615) 741-2718 or e-mail Controlled.SubstanceDatabase@state.tn.us

COMMON QUESTIONS AND ANSWERS

What if the pharmacy/dispenser did not fill any Schedule II, III, IV OR V prescriptions in the reporting period?
Please submit a zero report via the Web Upload Page, www.tnrxreport.com, indicating zero reports for Schedule II, III, IV or V prescriptions dispensed and specify the time period that you are reporting. Please see section 5 - Zero Reports for more information.

Are nursing home prescriptions required to be reported through the program?
Pharmacies dispensing to nursing homes are exempt from reporting. However, prescriptions dispensed to assisted living facilities are subject to reporting requirements.

Are hospital prescriptions required to be reported through the program?
Inpatient prescriptions dispensed are exempt. Outpatient prescriptions including employee prescriptions must be reported.

How are compounded prescriptions to be recorded?
Prescriptions compounded by the pharmacist and containing a controlled substance must be reported. The NDC number of the Schedule II, III, IV or V ingredient in the compounded product must appear in the NDC field and the actual metric quantity of the Schedule II, III, IV or V substance, used in the compounding is reported in the quantity field. If more than one covered substance is used in a compounded prescription, the amounts of each covered ingredient are added and the total is reported as the quantity. The NDC number is reported as eleven "9"s (99999999999).

What are exemptions to reporting?

- A Drug administered directly to a patient;
- Any drug dispensed by a licensed health care facility provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours;
- Any drug sample dispensed;
- Any facility that is registered by the United States drug enforcement administration as a narcotic treatment program and is subject to the record keeping provisions of 21 CFR 1304.24.
- Dispensing to inpatients in hospitals or nursing homes (exemption does not apply to assisted living)
- Dispensing to inpatients in hospices (exemption does not apply to home hospice or hospice in an assisted living facility)

If you consider that you are exempt from reporting or wish to submit a request for a waiver from reporting please fill out the attached exemption/waiver request form and mail to:

Department of Commerce and Insurance
Tennessee Board of Pharmacy
Controlled Substance Database
500 James Robertson Parkway
Nashville, TN 37243
Or submit by FAX to (615)741-2722

WHAT DATA IS MANDATORY, WHAT IS OPTIONAL?

Tennessee Annotated Code §**53-10-305** requires that each SCHEDULE II, III, IV, and V prescription submitted contain the following data:

1. Patient First Name.
2. Patient Last Name.
3. Patient Street Address.
4. Patient State.
5. Patient Zip Code (including 4 digit suffix, if available).
6. NDC Number.
7. Date Rx Filled.
8. Metric Quantity (ml, mg or # of tabs).
9. DEA number of pharmacy/dispenser
10. DEA number of Prescriber.
11. Patient Date of Birth
12. Prescription number.

ASAP R.5/95 Telecommunications Format for Controlled Substances

Field Name	Field Format	Field Length	Positions
Identifier	A/N	3	001 - 003
Bin	N	6	004 - 009
Version Number	N	2	010 - 011
Transaction Code	N	2	012 - 013
**DEA Number	A/N	12	014 – 025
Customer ID Number	A/N	20	026 - 045
Zip Code	A/N	3	046 - 048
**Birth Date	N	8	049 - 056
Sex Code	N	1	057 - 057
**Date Filled	N	8	058 - 065
**Rx Number	N	7	066 - 072
New - Refill Code	N	2	073 - 074
**Metric Quantity	N	5	075 - 079
Days Supply	N	3	080 - 082
Compound Code	N	1	083 - 083
**NDC Number	N	11	084 - 094
**Prescriber DEA Number	A/N	10	095 - 104
DEA Suffix	A/N	4	105 - 108
Date Rx Written	N	8	109 - 116
Number of Refills Authorized	N	2	117 - 118
Rx Origin Code	N	1	119 - 119
Customer Location	N	2	120 - 121
Diagnosis Code	A/N	7	122 - 128
Alternate Prescriber #	A/N	10	129 - 138
**Patient Last Name	A/N	15	139 - 153
**Patient First Name	A/N	15	154 - 168
**Patient Street Address	A/N	30	169 - 198
**Patient State	A/N	2	199 - 200
**Patient Zip Code (Extended)	A/N	9	201 - 209
Triplicate Serial Number	A/N	12	210 - 221
Filler	A/N	1	222

NOTE: All **A/N** fields must be left justified, right blank filled, and all **N** fields are right justified, left zero filled.
**** Required Field (applicable to the Tennessee Annotated Code §53-10-305).**

ASAP R.5/95 Telecommunications Format Field Definitions

Field Name	Definition	Values	R/O*
Identifier			**O**
BIN			**O**
Version Number			**O**
Transaction Code			**O**
DEA Number			**R**
Customer ID Number	Customer Identification Number.		**O**
Zip Code	3 digit US Postal Code identifying the state code		**O**
Birth Date	Customer's birth date	YYYYMMDD	**R**
Sex Code	Sex / Gender of the patient	1=Male 2=Female 3=Animal	**O**
Date Filled	Date the prescription was filled	YYYYMMDD	**R**
Rx #	Prescription number assigned by the pharmacy		**R**
New-Refill Code	Code indicating whether the prescription is new or refill		**O**
Metric Quantity	Number of metric units of drug being dispensed		**R**
Days Supply	Estimated number of days the prescription will last		**O**
Compound Code	Code indicating whether or not the prescription is a compound medication		**O**
NDC Number	National Drug Code of the drug dispensed	(5-4-2) format	**R**
Prescriber ID	DEA # of the prescribing physician		**R**
DEA Suffix	DEA Suffix		**O**
Date Rx Written	Date the Rx was written	YYYYMMDD	**O**
Number of Refills Authorized	Number of refills authorized by Prescriber		**O**
Rx Origin Code	Code indicating the origin of the prescription		**O**
Customer Location	Code indicating location of patient (customer)		**O**
Diagnosis Code	ICD-9 or CPT code provided by Prescriber		**O**
Alternate Prescriber	State license number or HIN. To be included if DEA number field is for an institution rather than the prescriber.		**O**
Patient Last Name	Patient Last Name		**R**
Patient First Name	Includes middle initial and suffix		**R**
Patient Address	Street or PO Box #		**R**
Patient State	Standard 2-digit State abbreviation (example: VA).		**R**
Patient Zip Code	Full zip code (including 4-digit suffix if available).		**R**
Triplicate Serial #	# Assigned to triplicate Rx document by States with triplicate programs.		**O**
Filler	Filler		**O**

***R = required O = optional**

NOTE:

1. Fixed length ASCII text files with one record (line) per prescription.
2. Carriage return at the end of each record.

Attachment 1
Program Transmittal Form

File Name: _____ Date: _____
The file name should be the DEA number followed by .DAT (example: AB01123456.DAT)

Pharmacy/Dispenser Name: _____

DEA Number: _____

Number of Prescriptions in File: _____

Name of person submitting report: _____

Phone Number: _____ Fax Number: _____

External/diskette label must contain: Pharmacy/Submitter Name, DEA Number and Number of Prescriptions

Attachment 2

DEPARTMENT OF COMMERCE AND INSURANCE
TENNESSEE BOARD OF PHARMACY
Controlled Substance Database
500 JAMES ROBERTSON PARKWAY
NASHVILLE, TENNESSEE 37243-1149
(615) 741-2718 OR FAX (615)741-2722

UNIVERSAL CLAIM FORM

DEA # _____

RX #	Date Rx Filled.	Metric Quantity	Patient Date of Birth	NDC Number	Prescribers DEA number	Patient First Name

Patient Last Name	Patient Street Address	Patient State	Patient Zip Code

RX #	Date Rx Filled.	Metric Quantity	Patient Date of Birth	NDC Number	Prescribers DEA number	Patient First Name

Patient Last Name	Patient Street Address	Patient State	Patient Zip Code

NOTE : The above form serves as an example only. Do not submit this form for reporting purposes.

Attachment 3

REQUEST FOR A WAIVER OR AN EXEMPTION FROM REPORTING FORM

DEPARTMENT OF COMMERCE AND INSURANCE
TENNESSEE BOARD OF PHARMACY
Controlled Substance Database
500 JAMES ROBERTSON PARKWAY
NASHVILLE, TENNESSEE 37243-1149
(615) 741-2718 OR FAX (615) 741-2722

REQUEST A WAIVER FOR ELECTRONIC REPORTING

Please provide the information requested below. (Print or Type)

Name of Dispenser/Pharmacy	Tennessee Board License Number	
Street Address	City	
State	Zip Code	Area Code and Telephone Number
Name of Pharmacist in Charge	Pharmacist in Charge Tennessee License Number	
Signature:	Date:	

Reason for approval of exemption/waiver request: (Check one box below)

☐ Hardship created by a natural disaster or other emergency beyond the control of the permit holder. Please attach description of hardship.

☐ This dispenser does not hold a Controlled Substance registration with Drug Enforcement Administration.

☐ This dispenser is exempt from reporting according to Rule 1140-11-.04(4)(5)

(4) If the dispenser does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the "ASAP Telecommunications Format for Controlled Substances", then the dispenser may request a waiver from the electronic reporting of the data from the Committee.

(5) If the Committee grants the dispenser a waiver from the electronic reporting requirement, then the dispenser shall comply with an alternative method of reporting the data as determined by the Committee, which is submitting the required data in writing on a form approved by the Committee.

☐ This dispenser is exempt from reporting according to T.C.A. §53-10-302(6)

"Dispense" means to physically deliver a controlled substance covered by this chapter to any person, Institution, or entity with the intent that it be consumed away from the premises in which it is dispensed. It does not include the act of writing a prescription by a practitioner to be filled at a pharmacy licensed by the board.

Type of Pharmacy (check One box below):

☐ Hospital
☐ Institution
☐ Nursing Home
☐ Other _____

☐ I hold a DEA Registration but do not dispense any controlled substances in normal course of my practice.

For Department Use Only

Date Received	☐ **Approved** ☐ **Disapproved**	**Director of Designee Signature**	**Date of Action**